

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

STUYVER, et al.

Serial No. 10/606,879

Filed: June 24, 2003

For: METHOD FOR TYPING AND DETECTING HBV



Atty. Ref.: 2551-123

Group: 1648

Examiner: Peng, Bo

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

June 14, 2007

Sir:

INFORMATION DISCLOSURE STATEMENT

- ☐ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**
[within 3 months of filing or prior to 1st Office Action on the merits]
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
N/C
- ☒ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**
[after Final Office Action or Allowance (requires Rule 97(e)
Statement and Rule 17(p) fee), but before final fee payment]
\$180.00

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180.00 OP

The following are submitted in the above-identified application in compliance with 37 C.F.R. §§ 1.97 and 1.98:

- ☒ 4. A list of documents on Form PTO-1449 is enclosed herewith. Copies of the listed "Other Documents" and WO 97/40193 and WO 94/26904 are being filed electronically with PTO PAIR. The listed other documents and WO applications, other than the noted claims and File Histories, are contained in the file history of Serial No. 10/453,792, where the documents are of record.

This paper is submitted in accordance with:

- ☐ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☒ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
- ☐ a) The required Statement made in item 8 below; or
- ☒ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
- ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
- ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
- ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
- ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37

CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

Respectfully submitted,
NIXON & VANDERHYE P.C.

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**INFORMATION DISCLOSURE
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(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	US 2004-0029110 A1	2-2004	Stuyver et al			
	6,709,812	3-2004	Stuyver et al			
	6,555,311	04/2003	Locarnini			
	2005-0175990	08/2005	Stuyver			

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
97/40193	10/1997	WO			
94/26904	11/1994	WO			

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	File History (FH) of U.S. application Serial No. 09/155,885 retrieved from USPTO IFW June 14, 2007
	File History (FH) of U.S. application Serial No. 10/453,792 retrieved from USPTO IFW June 14, 2007
	Claims of U.S. Serial No. 11/802,328 filed May 22, 2007
	Nature(1979), vol. 282, PASEK M <i>et al</i> , pp 575-9, "Hepatitis B virus genes and their expression in <i>E. Coli</i> " Figure 2. copy contained in attached FH of Serial No. 10/453,792
	Nucleic Acids Research(1983), vol. 11(6), ONO Y <i>et al</i> , pp 1747-57, "The complete nucleotide of the cloned hepatitis B virus DNA; subtype <i>adr</i> and <i>adw</i> " Figure 2 and 3. copy contained in attached FH of Serial No. 10/453,792
	J. General Virology (1988), vol. 69, VAUDIN M <i>et al</i> , pp 1383-9, "The complete nucleotide sequence of the genome of a hepatitis B virus isolated from a naturally infected chimpanzee" Figure 1. copy contained in attached FH of Serial No. 10/453,792
	J. General Virology (1988), vol 69, OKAMOTO F <i>et al</i> , pp. 2575-83, "Typing hepatitis B virus by homology in nucleotide sequence: comparison of surface antigen subtypes" Figure 1. copy contained in attached FH of Serial No. 10/453,792
	Gene (1988), vol. 64, RIVKINA M <i>et al</i> , pp. 285-96, "Nucleotide sequence of integrated hepatitis B virus DNA and human flanking regions in the genome of the PLC/PRF/5 cell line" Figure 5. copy contained in attached FH of Serial No. 10/453,792
	J General Virology (1993), vol. 74, NORDER H <i>et al</i> , pp 1341-8, "Genetic relatedness of hepatitis B viral strains of diverse geographical origin and natural variations in the primary structure of the surface antigen" Figure 2. copy contained in attached FH of Serial No. 10/453,792

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Form PTO-FB-A820 (Also PTO-1449)


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	J Medical Virology (1994), vol. 44(1), HORIKITA M <i>et al</i> , pp 96-103, "Differences in the entire nucleotide sequence between hepatitis B virus genomes from carriers positive for antibody to hepatitis B e antigen with and without active disease" Table IV. copy contained in attached FH of Serial No. 10/453,792
	GenBank Accession No. D50489, "Hepatitis B virus DNA, complete genome" (no date available). copy contained in attached FH of Serial No. 10/453,792
	J General Virology (1995), vol. 45, UCHIDA T <i>et al</i> , pp 247-52, "Complete nucleotide sequences and the characteristics of two hepatitis B virus mutants causing serologically negative acute or chronic hepatitis B: Page 249. copy contained in attached FH of Serial No. 10/453,792
	J General Virology (1996), vol. 3, ALEXOPOULOU A <i>et al</i> , pp 173-81, "Whole genome analysis of hepatitis B virus from four cases of fulminant hepatitis: genetic variability and its potential role in disease pathogenicity" Table 3. copy contained in attached FH of Serial No. 10/453,792
	J General Virology (1997), vol. 78, BOWYER S <i>et al</i> , pp 1719-29, "A unique segment of the hepatitis B virus group A genotype identified in isolates from South Africa" Figure 5 copy contained in attached FH of Serial No. 10/453,792
	Carman <i>et al</i> , "Vaccine-induced escape mutant ...", The Lancet, Vol. 336, 1990 (8711) pages 325-329. copy contained in attached FH of Serial No. 10/453,792
	Fujii <i>et al</i> , "Gly ¹⁴⁵ to Arg Substitution in HBs Antigen of ...", Biochemical and Biophysical Research Communications, Vol. 184, No. 3, May 15, 1992, pages 1152-1157. copy contained in attached FH of Serial No. 10/453,792
	Yamamoto <i>et al</i> , "Naturally Occurring Escape Mutants of Hepatitis B Virus with ...", Journal of Virology, Vol. 68, No. 4, April, 1994, pages 2671-2676. copy contained in attached FH of Serial No. 10/453,792
	Carman, "The clinical significance of surface antigen variants ...", Journal of Viral Hepatitis, 1997. 4 (Suppl. 1) 11-20. copy contained in attached FH of Serial No. 10/453,792
	Wang GT <i>et al</i> , Chung Hua I Hseuh Tsa Chih, "Sequencing of hepatitis B Virus DNA fragment coding major HBsAg of escape mutant", 1994 June 74(6) pages 355-357, 391 (PubMed English Abstract PMID 7994645) copy contained in attached FH of Serial No. 10/453,792
	Ren H <i>et al</i> , Chung Hua I Hseuh Tsa Chih, "Expression of 12 antibody escape mutants of hepatitis B virus surface antigen gene in mammalian cell by using an Epstein-Barr based vector", 1995 75(7) pages 396-398 (PubMed English Abstract PMID 7553156). copy contained in attached FH of Serial No. 10/453,792
	Chenault, "Patterns of nucleotide sequence variation among cauliflower mosaic virus isolates", (Biochimie 76:3-8, 1994) copy contained in attached FH of Serial No. 10/453,792
	Fischer, "Generation of Duck Hepatitis B Virus Polymerase Mutants through Site-Directed Mutagenesis....", (Antimicrobial Agents and Chemotherapy 40(8): 1957-1960, August 7, 1996 copy contained in attached FH of Serial No. 10/453,792
	Norder, "Complete Genomes, Phylogenetic Relatedness, and Structural Proteins of Six Strains of the Hepatitis B Virus, Four of Which Represent Two New Genotypes", (Virology 198: 489-503, 1994). copy contained in attached FH of Serial No. 10/453,792
	Bartholomew, "Hepatitis-B-Virus resistance to lamivudine given for recurrent infection after orthotopic liver transplantation", (Lancet 349: 20-22, January 1997). copy contained in attached FH of Serial No. 10/453,792
	Aye <i>et al</i> , "Hepatitis B virus polymerase mutations Famciclovir therapy in patients following liver transplantation", Hepatology Vol. 24, No. 4, Pt.2, September 1996. copy contained in attached FH of Serial No. 10/453,792
	Delaney <i>et al</i> , "Resistance of hepatitis B virus to antiviral drugs: current aspects and directions for future investigation", Antiviral Chemistry & Chemotherapy 12:1-35 (2001). copy contained in attached FH of Serial No. 10/453,792

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